Department of Health
Three Capitol Hill
Providence, RI 02908-5097
TTY: 711
www.health.ri.gov

14 May 2014

Patricia Rocha, Esq.
Adler Pollock & Sheehan
One Citizens Plaza, 8th Floor
Providence, RI 02903

Dear Ms. Rocha:

Attached is the Decision of the Director regarding the applications of MinuteClinic Diagnostic of Rhode Island, LLC (owned by MinuteClinic, LLC, which is owned by CVS Pharmacy, Inc., which is owned by CVS Caremark Corporation) for initial licensure to establish seven Organized Ambulatory Care Facilities in Woonsocket, Cranston, North Smithfield, East Greenwich, Providence, Wakefield and Westerly.

On 29 April 2014, the Health Services Council adopted the Report to the Health Services Council on the foregoing applications and recommended that these applications be approved. The state agency accepts the recommendation of the Health Services Council, adopts the attached Report in its entirety and hereby approves the applications with conditions as set forth in this Decision.

Please be advised that this approval is a pre-condition to licensure. Prior to actual licensure, the applicant must complete the appropriate licensure forms and submit them to the Office of Facilities Regulation in order to initiate final licensure activities.

If you have any questions, please contact Michael Dexter at (401) 222-2788.

Sincerely,

Michael Fine, MD
Director

Attachment

Rhode Island Department of Health

Decision With Conditions

Applications of MinuteClinic Diagnostic of Rhode Island, LLC (owned by MinuteClinic, LLC, which is owned by CVS Pharmacy, Inc., which is owned by CVS Caremark Corporation) for initial licensure to establish seven Organized Ambulatory Care Facilities in Woonsocket, Cranston, North Smithfield, East Greenwich, Providence, Wakefield and Westerly

MICHAEL FINE, MD

DIRECTOR OF HEALTH

MAY 14, 2014

INTRODUCTION

The Rhode Island Department of Health (hereinafter "state agency") is granted general powers and charged with certain duties there under to, *inter alia*:

> "take cognizance of the interests of life and health among the peoples of the state; shall make investigations into the causes of disease, the prevalence of epidemics and endemics among the people, the sources of mortality, the effect of localities, employments and all other conditions and circumstances on the public health, and do all in its power to ascertain the causes and the best means for the prevention and control of diseases or conditions detrimental to the public health, and adopt proper and expedient measures to prevent and control diseases and conditions detrimental to the public health in the state." RIGL Section 23-1-1

In deciding to approve the license application of MinuteClinic Diagnostics of Rhode Island, LLC to open seven (7) MinuteClinic locations in Rhode Island, and in determining the conditions upon which that approval depends, the state agency has carefully investigated and considered the effect these services will have on Rhode Islanders' access to primary care, and on the quality of patients' relationships with primary care providers within both the MinuteClinic and primary care practice settings. In assessing the expediency of conditions of licensure, the state agency addressed concerns regarding (1) potential conflicts and the appearance of conflicts of interest incident to the corporate structure and relationships between pharmacy and prescribers; (2) the potential fragmentation of primary care delivery and effect on the primary care business model; (3) the appropriateness of pediatric care in the MinuteClinic setting; and (4) patient access for underserved communities.

DISCUSSION

Competitive Markets, Regulation and Primary Care in Context

When a big box retailer builds on a highway near an old small city downtown, the results are predictable. A number of stores which kept the downtown alive go under, and a once vital neighborhood becomes increasingly unused, irrelevant and derelict. People, as consumers, get better prices, at least in the short term, and are able to buy more things, and perhaps there is an improvement in the part of people's lives related to having and consuming more.

With any market change, there are winners and losers. In the case of the big box retailer, investors in a distant place improve their return on investment, prices lower over all, there is an extraction of capital from localities which is concentrated elsewhere, usually in urban places, and the texture of life in small cities and towns changes forever. Gradually, the life of people and communities in small places withers, replaced by the lives of consumers in big cities. If what we measure is price and economic activity, the market has improved our economy. But if what we measure is the value of social relationships fostered by the interconnectedness of small places, we have emerged poorer than when this process began a value, that can be measured by worsened public health outcomes.

Nonetheless, CVS is not a big box retailer, and healthcare -- whether conducted in a MinuteClinic or otherwise -- functions in a professional and ethical environment different from the more commercially driven business environment of retail. CVS is a great Rhode Island health care company, and has led the nation in transforming the role of pharmacy retailers by increasingly pointing pharmacy retailing towards a public health orientation by, to cite two examples, moving away from selling tobacco products, and towards providing access for vaccinations. Meanwhile, it has achieved real success in achieving cost savings for insurers by the active management of pharmaceutical costs.

Health care does and must function in a market guided by appropriate regulation. It is the role of public regulators to take into account the overarching value and importance of directing the market for health care services so as to serve the primary and critical function, in a democracy, of protecting the health and safety of all its citizens so that they can effectively participate in the democratic process.

The State's role in overseeing health care delivery is deeply imbedded in statute and regulation which direct the state agency to regulate both the marketplace and the role and functions of health care professionals; so all Rhode Islanders receive both care and advocacy on the part of health professionals and institutions in a manner as free of provider self interest as possible. The Department of Health is specifically charged with the role of considering and helping to effectuate the development of a health services delivery system that is balanced, affordable, effective, and accessible, so that we care equally for the poor and excluded, and so that we ensure that health care professional providers have the competence, character and commitment to a community and public health focus. The better we do this, the more health services professionals and institutions will contribute reliably and effectively in providing the care of our entire population over time, thereby improving health and health outcomes for all.

From the perspective of health policy, Rhode Island has made the development of a strong primary medical care delivery system the centerpiece of our planning for the health care system of the future.

Primary care is medical care that is first-contact, comprehensive and continuous; that coordinates other forms of health care while providing care for the undifferentiated patient, the person who has not been diagnosed or the person whose situation may not fit into or require a diagnosis.[i] Primary care based delivery systems around the nation and around the world create the best population health outcomes at the lowest cost.[ii] Primary care is effective because it provides easy access to medical services, community by community, and also because it is the best form of medical care to address the bulk of the medical problems that impact population health measures. Cancers; accidental injuries, including drug overdose deaths; diabetes; heart disease and stroke; and asthma are the byproducts of our social organization, personal behaviors and genetics. Primary care practices are effective also because they leverage the relationship with patients that are built over time to effect behavior change and to help people compensate for genetic risks.

Although Rhode Island ranks eighth in the nation for primary care supply, and despite an increase in the proportion of the health insurance dollars directed toward primary care by the Office of the Health Insurance Commissioner, as well as a number of interventions meant to strengthen and develop that infrastructure, our public health outcomes are not appreciably better, nor are our health care costs any lower, than other states or nations.

Many initiatives intended to support and strengthen primary care have unintentionally but collectively created an environment that burdens (if not undermines) many primary care practices and challenges our ability to strengthen our delivery system overall. The cost and time required to employ electronic medical records, the evolution of the patient centered medical home and the demands on primary care practice, workflow and ecology that the patient centered medical home creates, together with increasing pressure from insurers for case management, chronic disease management and utilization management have deeply stressed primary care practices and disrupted the primary care business model. Many practitioners provide better individual patient care but at the cost of seeing fewer patients, which results in reduced fee for service income. Many primary care practitioners report working longer hours – but have seen little or no significant increases in income compared to the increases in net income experienced by primary care physicians and providers in surrounding states.

Accordingly, serious consideration has been given to the issue of MinuteClinic's potential to erode the underpinnings of the primary care practice model.

Primary care practices have been significantly undercapitalized for many years, challenged by the necessity of functioning as businesses in a world in which they have little effective market power (in part because they are constrained by our regulation of commerce, as discussed below), yet they are obligated to meet regulated standards of professional practice -- and they are also constrained by the ethical commitments which cause us to value them. In addition, physicians are prohibited from making and profiting

from self-referrals and from selling pharmaceutical products. Except for physicians operating in group practices, they are prevented by statute from owning laboratories or imaging facilities -- business arrangements common in veterinary medicine -- because of legitimate concerns about potential conflicts of interest or the appearance of such conflicts. Physicians are not allowed to combine in order to bargain with insurers outside of the formation of group practices; only very large group practices have enough market power to counterbalance the market power of insurers effectively, and even large group practices are constrained by the anti-trust laws from becoming so large that they have market dominance. [iii] In addition, although contending with agonizingly slim business margins, primary care physicians, nurse-practitioners, and physicians' assistants who own and run their own practices are required by regulation, by professional codes and by their own ethical commitments to the patients they serve to ensure that patients are not abandoned, whatever the business cost.

Given these legal restrictions, it is no surprise that primary care physicians and practices generally have not consolidated, and thus lack the ability to invest in new infrastructure and develop new services. We desperately need to bring new sources of capital investment to build a primary care delivery system that is adequate to address Rhode Island's needs. We need capitalization, service delivery standards, quality expectations and measures, a robust electronic information system and investment in workforce development if Rhode Island is to achieve population health improvement. Rhode Island must also achieve medical cost savings to rebuild our economy.

Thus, it is also no surprise that the request by CVS to enter a market place previously occupied mostly by primary care practices has created consternation among some in the primary care physician community. It is not clear, however, that denying the requested entry of MinuteClinic into Rhode Island has any hope of achieving the goals that we have set for the primary care community or that the primary care community has set for itself.

Even more, it is not clear that it is in the public interest to deny Rhode Islanders -- as patients and as consumers -- choice in accessing health care, even if that choice challenges the already vulnerable business model of primary care in Rhode Island. Not all Rhode Islanders have or use primary care now.[iv] Despite the public health value of maintaining and expanding strong relationships between patients and their primary care providers, any adverse impact MinuteClinic may have in that regard must be weighed in balance with the fact that access for patients will be enhanced for some services.

There is testimony on the record that MinuteClinic is likely to adversely impact the business model of primary care, but there was no evidence provided that such damage has occurred around the country. There is testimony, on the record, that MinuteClinic will impede the development of the patient centered medical home. However, there was no evidence provided that this has occurred elsewhere and no evidence offered showing

that the patient centered medical home has effectively improved outcomes and reduced costs for populations as large as the population of the State of Rhode Island. The Department takes administrative notice of evidence showing those advantages for smaller populations, in demonstration projects, but also notes that larger and better-controlled clinical trials have produced equivocal results. [v]

The primary care community of Rhode Island, tired and trapped as it is, still has the ability to exert major, and even profound, influence on public policy when it speaks with one voice, and when that voice expresses un-self interested advocacy. For example, it is possible that the objections of the primary care community about the sale of tobacco products by a provider of primary care services during CVS's prior application for MinuteClinic licensure in Rhode Island, had some influence on the corporation, and helped CVS' decision to take the nation in a new direction. By going tobacco free, CVS is exemplifying the notion of health in all policies, and is leading the real world development of a new ethical construction for health care market players.

The primary care community, acting together in the interest of patient care, should be able to evolve new models of primary care delivery that will make trivial any damage caused to their business model from MinuteClinic. There is room in the market for both. MinuteClinic provides evidence of a consumer demand that is not being met in the current health services delivery marketplace. Response to that demand should not be suppressed but rather be embraced, if the term "patient -- centric" is to have any meaning at all.

ISSUES PRESENTED

On April 29, 2014, the Health Services Council (hereinafter "the council") voted to recommend acceptance of the application of the MinuteClinic Diagnostics of Rhode Island, LLC for initial licensure of seven (7) organized ambulatory care facilities in Woonsocket, Cranston, North Smithfield, East Greenwich, Providence, Wakefield and Westerly, by a vote of eleven (11) to one (1), with two (2) abstaining. The acting chair of the council, and other members, asked that, in considering this recommendation, the state agency consider and comment on three (3) issues: (1) the ethical implication of having a prescriber of medicine be part of a corporate enterprise which also owned the pharmacy in which the clinical provider was located; (2) the need for organization of an individual's health care, and the risk that the retail clinic model might fragment that care and; (3) the issue of pediatric care, including the appropriateness of providing school physicals, as proposed to be provided by MinuteClinic. The state authority also considered (4) the issue of patient access both in terms of impacts on the primary care business model and in terms of underserved communities, particularly as part of its review of applicant's offer

of charity care. In addition, the council recommended the adoption of certain conditions of approval.

I. Ethics

The state agency undertook a careful analysis of the ethical implications of providing care within a facility owned by a corporate entity that also owns the pharmacy in which the clinic is located. Such a construction creates the appearance of a conflict of interest *prima facie*, and raises concern about self-referral. MinuteClinic argues that the existence of separate corporate entities creates a safe harbor under Federal "anti-kickback" statutes (42 USC § 1320a-7b(b)), but the appearance of a conflict remains. MinuteClinic has, however, successfully addressed that appearance by creating policies and procedures that mitigate the risk of any potential conflict – clear disclosures that any generated prescription can be transmitted to any pharmacy or issued in written form, and policies that require clinicians to offer all patients that option. These excellent and ethical policies and procedures shall be maintained as a condition of licensure.

At least one public comment, and some council discussion addresses the existence of Rhode Island law prohibiting prescribers from owning more than ten (10) percent of any pharmacy or drug store. [vi] Because no prescriber has a greater than ten (10) percent ownership interest in CVS-Caremark, that statute is not applicable here. While there is a clear asymmetry (a pharmacy retailer is allowed to own a clinic, but a prescriber is not allowed to own a pharmacy), the legal asymmetry does not reflect an ethical compromise as long as MinuteClinic's current policies and procedures remain in effect. There is no statutory or regulatory authority granted to the licensing authority to address a market asymmetry, no matter how unfair this may seem.

II. Fragmentation of Patient Care

The issue of potential fragmentation of care was raised by members of the council, and in public comments. Fragmentation, although not formally defined by either council members or public comment, is taken to mean lost opportunities for relationship continuity over time wherein a patient, who has a primary care physician, is seen for primary care issues by providers other than the primary care physician, and represents a lost opportunity for prevention according to established, evidence-based guidelines, and for relationship building and maintenance. The average patient sees his or her primary care physicians only one (1) or two (2) times a year. Those visits, for whatever other additional purposes, must accommodate screening for many diseases and conditions, including behavioral health and substance abuse issues, as well as provide the interpersonal check-in that helps the physician or other provider track the person who is the patient over her or his life course, and enter into that person's narrative. Fragmentation is relevant only for those persons who have an established primary care relationship, a choice not all Rhode Islanders make. Accordingly, it will not be an issue for every MinuteClinic patient. In

considering the issue of fragmentation, the state agency takes administrative notice of the public health benefits of primary care previously discussed.

No evidence was cited in public comment that such fragmentation – or injury to public health attributable to other factors – occurs in other parts of the country where MinuteClinic is currently established. There also was not any evidence presented by MinuteClinic that either fragmentation does not occur, or that there is measurable public health benefit from MinuteClinic's services, MinuteClinic has a major role in the distribution of vaccines, and CVS plays a major role in immunizing the population against influenza, both seasonal influenza and H1N1 strains.

There are significant scientific challenges to the acquisition of such evidence, which would require a very large population carefully tracked over many years. MinuteClinic did endorse the Patient-Centered Medical Home concept in a number of its representations, however, there is no need in the instant case for such evidence, and the state agency deems that there is consensus that fragmentation of care should be avoided wherever possible for patients who have an established primary care relationship.

Conditions which provide for the rapid and full exchange of information, such as requiring MinuteClinic to develop and maintain electronic linkages to primary care providers, to identify the primary care provider, and to submit a visit record rapidly (and electronically) to that provider, help mitigate the adverse effects of the fragmentation inherent in the use of retail based clinics. Nonetheless, these conditions will not address the adverse impact of such care on the continuity of the primary care relationship, because each retail clinic visit represents a potential missed opportunity for prevention and for the maintenance of the primary care relationship, while necessitating extra work for the primary care provider, who must review and process the information submitted without reimbursement. Thus, some fragmentation will unavoidably occur, despite the intended effectiveness of the most comprehensive conditions.

At the same time, the impact of that fragmentation is balanced by the potential benefit that MinuteClinic offers to those Rhode Islanders who lack a primary care relationship, and the competitive pressure for the improvement of the patient experience that MinuteClinic represents.

The best means to address the risk of fragmentation lies not in regulation, but in the potential primary care practices have to develop open access and extended hours so the care they provide is as convenient or more convenient than the care MinuteClinic promises to provide, and in their ability to educate their patients about the benefits of the relationship they do provide.

III. Pediatric Care

Similar to fragmentation, concerns about the care rendered to children were raised by council members and in public comments. In addition, the positions of the American Academy of Pediatrics, The Rhode Island Medical Society, and the Rhode Island Academy of Family Physicians were placed into evidence.

Theoretical concerns other than fragmentation about the impact of MinuteClinic on child health can be summarized as follows: child health is a dynamic process, with critical interdependent developmental milestones required for a child to grow and develop normally, enter school ready to learn, benefit from education and modeling for emotional maturation, and emerge as a mature, fully functional adult. While the current health of adults is at risk from illness and occasionally depends on skillful medical care, both the current health and the growth potential of a child is put at risk by illness, and that the growth potential of a child is put at risk by missed opportunities to identify developmental arrests, which can be caused by disease, by inborn errors of metabolism, by birth defects, or by environmental or emotional toxins. From the perspective of growth and development, the most important period of a child's life is zero (0) to six (6) years, when the child learns to stand and walk, to speak and reason, to interact with her or his environment, and to develop and maintain relationships with others.

Appropriate child health care involves a complex series of regular vaccinations to prevent disease, anticipatory guidance, parent education, and screening for inborn errors of metabolism, lead poisoning, and regular formal developmental screenings using standardized tools for that assessment. MinuteClinic provides vaccinations, but does not provide them in the context of an organized sequence of child health surveillance, with screening, assessment and testing performed at regular intervals.

Performing vaccinations or other testing outside of the organized sequence of preventive care described above creates a putative public health risk. If a child receives only MinuteClinic care, it might be argued, the child, his or her parents, and the community in which all live miss the opportunity for early intervention and treatment. Most child health providers track interval compliance with this preventive scenario, and work to maintain adherence to the organized sequence of screening and vaccination, in order to recognize disease or dysfunction early, so that intervention can begin before snowballing developmental delay is significant. A child's attendance at MinuteClinic, may be further argued, represents a missed opportunity for staged preventive and developmental treatment, and for scheduling the subsequent screening in the sequence at the next interval. The supposed risk of fragmentation of care is compounded by the putative risk of missed opportunities for early diagnosis, treatment or intervention, and many more years of fully functional life chances lost.

But putative risks are not actual harms. On the one hand, there is no evidence placed on the record that MinuteClinic care results in any compromise of child health whatsoever. On the other hand, there is no evidence that the risk of and any potential harm to child health has ever been formally studied. MinuteClinic might argue that their experience of twenty million patient visits argues against a concern about risk. But lead poisoning, vaccine for preventable illness, developmental delays from missed inborn errors of metabolism, birth defects, and environmental and emotional toxins are quite rare events - rare events that emerge slowly with little obvious association between cause and disorder. Further, MinuteClinic patients are scattered over twenty eight states, so that patterns of disease associated with MinuteClinic use would be hard to detect in any one population.

Thus, the claim that since we have yet to see a problem, no problem is likely to exist, appears to be scientifically and epidemiologically specious, at least so far as the impact of MinuteClinic care on child health is concerned. The impact of MinuteClinic care is unknown, and will likely remain unknown until it is formally studied, looking at the vaccination rates, lead screening rates, and developmental assessment rates in a population of children zero (0) to six (6), using these rates as process indicators of adequate care. The incidence and prevalence of rare morbidity makes the study of outcomes very difficult indeed.

Three lines of reasoning might be used to assess the ability of MinuteClinic to see and treat children: the weight of expert opinion; the importance of the qualifications of providers for child health; and the precautionary principle.

Expert opinion is that MinuteClinic should not see children of any age. The state agency looked closely at the recommendations of professional organizations, while taking administrative notice of the potential for bias based on self interest. The American Academy of Pediatrics, for example, is the nation's most reputable organization with expertise in pediatrics, but its recommendations about retail-based clinics need to be considered with caution, because no clinical evidence is cited in support of the recommendations offered

The main recommendation of the American Academy of Pediatrics is that retail-based clinics "are an inappropriate source of primary care for pediatric patients" but no clinical evidence is cited in support of that recommendation.[vii] The statement of the Rhode Island Medical Society, that retail based clinics should not care for children younger than six (6), also cites no evidence in support of its recommendation. [viii] Both organizations are organizations of professionals who are potential business competitors with retail-based clinics (although both include professionals who are also described by MinuteClinic as collaborators needed for the operation of their business model). Because of the potential for self-interest bias, and the absence of an evidence base for these recommendations, these recommendations cannot be given convincing weight as expert opinion.

Council members explored the qualifications of MinuteClinic to see children. Rhode Island law does not discriminate between a provider's scope of practice, however, and no evidence was offered or appears to exist supporting the notion that professional preparation adversely impacts the individual or public health outcomes of children's medical care. MinuteClinic cited one study that shows no difference in early return visits for children with otitis media. [ix] The evidence that does exists supports the ability of MinuteClinic to see children with otitis media, and there is no reason to believe that further study is likely to detect a significant disease by disease difference in outcome based on type of provider.

The precautionary principle in public health appears to apply here, however, and could be used to guide this Decision. The precautionary principle states that if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful falls on those taking an action.[x] The precautionary principle is best employed when the risk involves harm that is irreversible, even though the risk itself is speculative, and is particularly useful when the potential gain is small. Here, in the case of children younger than age six (6), the potential risk is unknown, but the potential harm (undiagnosed lead poisoning, the long term impact of

undiagnosed birth defects on normal growth and development, and the long term impact of vaccine preventable disease), is great and often irreversible. The potential gain to society of having children zero (0) to six (6) treated at a MinuteClinic is relatively small in a state where there is good to excellent access to pediatric care (convenience to parents, possible lower cost), although the potential gain to employees of MinuteClinic and stockholders of CVS-Caremark may be greater.

Even if MinuteClinic were barred from seeing all children under age six (6), there is no way to be sure that these children would be otherwise seen in a primary care practice when they were not being seen at MinuteClinic. For simple episodic illness, especially those that occur after hours, children are just as likely to be seen in Urgent Care Centers or in the Emergency Department of hospitals; thus, we have no way of demonstrating that any potential harm associated with a missed primary care visit would be prevented by excluding MinuteClinic from the care of these children. So it is not appropriate to invoke the precautionary principle as a reason to reduce MinuteClinic's requested scope of services or restrict MinuteClinic from the care of children.

Still, the evidence about the impact of scope of service for retail-based clinics may yet emerge, and it is important that we maintain the ability to change the permissible scope of service should new evidence be developed. [See Condition 10]

To partially but incompletely address concerns about fragmentation of pediatric care, Condition 7 requires that each MinuteClinic location be enrolled in Kidsnet before any vaccination is administered, and requires that each MinuteClinic enter all vaccinations of children into Kidsnet. Condition 15 requires that each MinuteClinic be enrolled in CurrentCare, and Condition 12 requires that when a patient has a primary care provider, and the patient gives permission, the medical record be transmitted, mailed or faxed to the primary care practice within 24 hours of the visit.

Concerns about school health and sports physical examinations are addressed here as a subset of pediatric care, although issues of care fragmentation are also implicated. These types of physicals are most likely to occur in MinuteClinic for children and adolescents who do not have a primary care relationship, or for youth who were not scheduled for routine physical examinations with their primary care physicians in a timely manner and then run up against deadlines that result in exclusion from school enrollment or sports participation.

Adolescents are the pediatric population group least likely to receive regular primary care[xi], so that every medical visit of an adolescent represents an opportunity for prevention and anticipatory guidance, and every medical visit by an adolescent that occurs outside of a primary care relationship likely represents a missed opportunity for prevention. On the other hand, adolescents are not known to follow instructions, regardless of the source, so the likelihood of improving the primary care relationship by closing any door to medical care is small. To this end, the public health strategy for improving prevention in adolescents has been to take medical care to adolescents, through school based clinics and programs like "Vaccinate Before You Graduate." These programs also undercut the maintenance of the primacy care relationship, but also have public health benefit, and, like MinuteClinic, they reach youth who do not have a primary care relationship. There is an significant tension between the requirements of maintaining a good

primary care relationship, and getting school and sports physicals and vaccinations done for adolescents, a tension that is likely only resolvable by the creation of school-based clinics in every Rhode Island high school that are linked to the primary care medical home. Short of that innovation, the primary care and public health of adolescents will remain inadequate, MinuteClinic notwithstanding.

While it is likely that MinuteClinic school and sports physicals will fragment the primary care relationship to some extent, the weight of evidence does not support prohibiting them in retail-based clinics, because for adolescents, an "any open door" policy appears to be the most effective public health strategy available. Instead, primary care practices have the opportunity to improve access to care for this group by using improved scheduling approaches; to better market the value of the primary care relationship to their patients, to parents and to the community; and have the opportunity to advocate with payers for co payment and deductible policies that encourage and support the primary care relationship. Such advocacy will be supported by the state agency. In addition, this issue is addressed by Condition 18, which requires MinuteClinic to include developmentally appropriate prevention messages as part of any pediatric visit.

IV. Patient Access

Of concern, from a public health perspective, are those patients who do not choose to have a primary care relationship, for whom people MinuteClinic refers to primary care routinely, a process that is memorialized in a Condition because of its public health value. Contrary to MinuteClinic's representations, there is no documented shortage of primary care in Rhode Island, which ranks eighth in the nation for primary care supply. But there is also no reason to think that primary care practice is evenly distributed across the state, or that supply will be able to keep up with new demands imposed by the Affordable Care Act or changes in the incidence and prevalence of disease, and by the development of new technologies which bring with them new primary care responsibilities and added workload.

Yet, the safety of MinuteClinic's clinical model depends on the existence of a robust primary care infrastructure, so there are an adequate number of primary care medical homes for patients to be referred to or referred back to, should their presenting complaint not be within MinuteClinic's scope of services, should they be presenting for the care of mental and/behavioral health concerns (which represent 28-56 percent of the current primary care workload,) or should the patient have complex or serious medical conditions.[xii]

Conditions 1, 2, 4 and 5 address these concerns. Each MinuteClinic location will be required to maintain a roster of primary care practices within a five (5) mile radius that are accepting new patients. Should that roster be empty at any one time in a calendar year, MinuteClinic Diagnostics, LLC will be required to make an annual $25,000 payment to the Rhode Island Primary Care Loan Repayment Fund, which will be used for the recruitment and retention of primary care professional staff.

One public comment requested that all MinuteClinics referrals to primary care be to community health centers, a request that cannot be supported in a policy environment that has chosen marketplace competition as a formative element.

A number of public comments also addressed the potential harm that MinuteClinic might pose to the business model of primary care practices. No evidence was offered in support of this contention, and MinuteClinic offered letters of support from large health care systems, letters which might be taken to suggest that no such harm occurs. The relevance of these letters to the question of business model harm is unclear, however, because the practices at greatest risk are small practices, many of which are independent.

There is good reason to think that the potential harm to the small practice business model might actually occur. Small primary care practices operate on thin margins. They use their fee for service income to support the entirety of their operation: to pay their rent, pay their staff, run an expensive billing operation, pay their answering services so they can cover their practices 24 hours a day, and to cross subsidize the patients they care for who can't afford to pay them – often six (6) to ten (10) percent of their patient population. [xiii] The tiny margins created by a quick visit for a sore throat or an ear infection subsidize the care of patients with complex chronic diseases, or of children with behavioral issues caused by chaos at home, and others who need more time than the insurance company payment supports. There is no easy way to measure the business model impact of the loss of revenue from these more routine visits which are likely to comprise a portion of MinuteClinic's income. There is no way to predict how many practices will go out of business and no way to know how many practitioners will have to work still harder to make ends meet.

Unfortunately, there is also no ethical or legal way to protect these primary care practices from the business pressure created by the juggernaut of for-profit health care. The department simply lacks the authority – either pro-active or in response to licensing requests -- to intervene so as to protect the public purpose and value of primary care per se. For the moment, society seems to have chosen a marketplace approach to health care, and because of the cultural and legal environment accompanying this choice, there exists no legal or political space to protect the integrity of that public purpose or of the patient physician relationship, unless and until society makes another choice.

On the other hand, the concerns of a number of the public comments seem misdirected. MinuteClinic is a well thought out, well organized (albeit limited) practice model that focuses on quality, with a public health impact that is likely to be small but real. Viewed from a delivery system perspective, much of current primary care practice is an unconsolidated, patchy distribution of variable services with uncertain quality and no consistent service delivery or architecture. Nonetheless, a somewhat larger, if inconsistent, public health impact is achieved through offering services that are often as provider centric as they are patient and community centered – but also offering a set of services that include moments of deep intimacy and advocacy, ongoing relationship, and remarkable human commitment in the face of overwhelming odds.

The presence or absence of MinuteClinic in Rhode Island alone is not likely to sink or save the business model of primary care. Only through public engagement with communities, through building a well thought out, well organized practice model that focuses on quality and universal service, and reconstructed legal and ethical foundations of health care can we evolve a business environment that supports intimacy, advocacy, ongoing relationship, and human commitment, and offers the hope of protecting those cherished values.

Regarding patient access as a function of charity care, the council recommended a condition that the applicant establish and put into effect formal agreements for referral of charity care cases with a minimum of one (1) licensed free clinic within sixty (60) days of approval. That condition reflects MinuteClinic's commitment to provide up to $100,000 of free care to patients registered as active patients of the Rhode Island Free Clinic.

Section 23-17-14.3 (4) of Rhode Island General Laws lists "the extent to which the facility will provide or will continue to provide appropriate access with respect to traditionally underserved populations and in consideration of the proposed continuation or termination of health care services by the health care facility" as one criterion that must be specifically considered by the council.

It is difficult to determine what constitutes appropriate access to retail based clinic services with respect to traditionally underserved populations. These services duplicate services already available but make those services more accessible while also possibly contributing to the fragmentation of the primary care relationship. Those services may also provide affordable access to those Rhode Islanders who lack a primary care relationship. For lack of a better descriptor, the state agency determines that appropriate access for traditionally underserved populations to retail based services is equal initial access for those populations. In this light, it is noted as of particular value that MinuteClinic will accept Medicaid and all major Rhode Island health plans with a RiteCare product.

But the relationship with the Rhode Island Free Clinic, which has one (1) location and a limited patient roster, does not appear to offer appropriate access envisioned by statute to underserved populations by an organization with seven locations. Thus, condition 22 requires MinuteClinic to offer charity care services to any patient who has qualified for free care from the Rhode Island Free Clinic, a Rhode Island hospital (which is required to offer free care for any patient earning less than 200 percent of the federal poverty level) or a Rhode Island community health center, upon presentation of documentation from the Rhode Island Free Clinic, any Rhode Island hospital, or any Rhode Island community health center or community mental health center, so long as said documentation is dated within one year of the date the patient presents to the MinuteClinic for care. Because of the need for adequate primary care, however, the MinuteClinic shall not be responsible for patients presenting for charity care for more than two (2) times within one calendar year at any MinuteClinic site.

DECISION

The State Agency approves the application of MinuteClinic Diagnostics LLC to license seven (7) health care facilities located at Woonsocket, Cranston, North Smithfield, East Greenwich, Providence, Wakefield and Westerly with conditions as rendered below. The character, commitment, competence, and standing in the community of the applicant is well documented. It is not likely that these licenses will impact the viability of the applicant, and it is likely that these facilities will provide safe and adequate treatment for individuals receiving the health care facilities service, except as indicated below. In complying with the conditions below, the facilities will provide appropriate access to traditionally underserved populations.

In response to issues raised by the council and in public comments, the appearance of conflict of interest that results from co-locating clinical and pharmacy services in a facility owned by a single corporate entity is addressed by actions offered to be taken by the applicant, actions which are memorialized in this decision as a condition of licensure.

It is likely that fragmentation of the health care of some individuals will occur, and that MinuteClinic's entry into the Rhode Island market will impact the business model of some of Rhode Island's primary care providers adversely. The risk of fragmentation of care afforded to some individuals is balanced by access to care afforded to other individuals, so the net population impact, although unpredictable, is not likely to be adverse. Damage to the business model of Rhode Island's primary care practices is concerning, given the business pressure they already experience, but the authorizing statute for this action, Chapter 23-17-14.3 of Rhode Island General Law, does not instruct the state agency to make a determination based on that criteria. We call attention to that likely damage, which does impact the core of Rhode Island's health policy strategy, recognizing that public intervention is necessary to support the significant public purpose of primary care, if Rhode Island is to evolve a health care system that is effective, affordable, rational, personal and just.

CONDITIONS

Approval of MinuteClinics request for licensure is contingent upon MinuteClinic's acceptance of the following conditions, which are intended to maintain a level playing field, to protect the health and safety of all Rhode Islanders, to provide for robust and fair maintenance of the health services safety net for the poor and excluded, to prevent conflicts of interest by health care providers, to develop a balanced health care system, and to ensure the seamless and confidential flow of personal health information to facilitate the best patient care.

1. The applicant shall ensure that each MinuteClinic maintains a current roster of primary care practitioners, including community health centers, who are currently accepting new patients, and who are willing to accept a referral from a MinuteClinic to serve as a primary care provider.

2. The applicant shall ensure that each MinuteClinic provides each patient who does not have a primary care provider with a referral from the list maintained in accordance with condition number 1.

3. The applicant shall ensure that each MinuteClinic only provides care and treatment to children eighteen (18) months and older.

4. In each Calendar year the applicant shall report to the Department, if there are no available primary care providers within a five (5) mile radius accepting patient referrals at any time during the calendar year from MinuteClinics.

5. For each MinuteClinic where the MinuteClinic cannot locate a primary care provider within a five (5) mile radius to accept referred patients, the applicant shall annually contribute twenty five thousand dollars ($25,000.00) to the Rhode Island Physician's Loan Replacement Fund.

6. The applicant shall ensure that for children over eighteen(18) months old and under nineteen (19) years old ("Minors"), if the purpose of the MinuteClinic visit is for a childhood immunization, the MinuteClinic shall counsel the parent or guardian on the importance of establishing and maintaining a relationship with a Primary Care Physician for ongoing medical and well-child care.

7. The applicant shall ensure that each MinuteClinic enrolls in Kidsnet and maintains documentation of the transmission and enters the vaccination information into Kidsnet within twenty-four (24) hours. No MinuteClinic shall administer vaccinations to Minors until the MinuteClinic is enrolled in Kidsnet.

8. The applicant shall ensure that MinuteClinic identifies and limits to three (3) repeat encounters each year with individual patients for the same treatment condition or illness.

9. Each MinuteClinic's scope of practice is limited to the "MinuteClinic Scope of Practice" contained in attachment A of this document.

10. A change in MinuteClinic's scope of practice may be sought if new data and/or best practices emerge supported by research and statistical analysis indicating that MinuteClinic's scope of practice should be altered in anyway. Such new evidence shall be presented to the Department for final review and approval in any way.

11. The applicant shall ensure that each MinuteClinic prominently posts or otherwise discloses in English and in Spanish a description of the services that are provided and shall provide a clear statement that indicates that the patient should seek care from his or her primary care provider for other complaints whose needs exceed the MinuteClinic's services.

12. The applicant shall ensure that each MinuteClinic provides a copy of the medical record of each visit to the patient at the end of the visit, and with the patient's consent, provides a facsimile or electronically transmitted copy of the medical record of the visit to the patient's primary care provider, if any, within twenty-four (24) hours of the visit. Such copies or transmissions shall be provided at no charge to the patient.

13. The applicant shall ensure that each MinuteClinic prominently posts in English and in Spanish a statement indicating that the patient may obtain any prescription medications or other recommended supplies at any location and is not required to purchase such supplies from the CVS host retail location. Such statement shall be included on each prescription and shall also be orally communicated to each MinuteClinic patient.

14. The applicant shall ensure that each MinuteClinic has a collaborating Physician licensed to practice medicine in the State of Rhode Island available for staff collaboration during all hours the MinuteClinic is open for business. Any health professional who participates in the on-call after hours service shall be licensed to practice in the State of Rhode Island. All Physician Assistants employed at the MinuteClinic shall be supervised by a physician licensed to practice medicine in the State of Rhode Island. All collaborating and supervising Physicians shall be licensed to practice medicine in the State of Rhode Island.

15. The applicant shall ensure that each MinuteClinic provides each patient with the opportunity, and, if the patient desires to enroll, with assistance in enrolling in CurrentCare. Any patient who

desires to review or revise the status of his or her enrollment shall likewise be offered assistance in doing so.

16. The applicant shall ensure that all Physicians, Nurse Practitioners, Physicians Assistants and qualified prescribers employed by each MinuteClinic are enrolled into Currentcare and the Prescription Monitoring Program. All qualified prescribers employed by the applicant shall consult with the Prescription Monitoring Program before prescribing any scheduled medications.

17. The applicant shall ensure that each MinuteClinic has an Electronic Medical Record that is fully integrated with the various EPIC systems utilized by Rhode Island Hospitals within six (6) months of each of the Hospitals going live with EPIC.

18. The applicant shall ensure that each MinuteClinic provides all Minors at the time of treatment with a minimum of two (2) age appropriate preventive health care information/messages. Such information shall be reviewed and approved by the Department.

19. The applicant shall ensure that each MinuteClinic reports to the Department of Health annually, by January 15 for the prior year the percent of MinuteClinic patients who were prescribed antibiotics by a MinuteClinic provider. The report shall include by percentage a delineation of the types of antibiotics prescribed by groupings of patented and generic products.

20. The applicant shall ensure that each MinuteClinic prominently displays in a location visible to patients, in plain language in both English and Spanish, a disclosure of any rewards, inducements, penalties, disincentives or other policies applied to MinuteClinic or its employees by CVS regarding prescribing or prescription dispensing practices or relationships, including, but not limited to rewards for prescribers based on per patient rates of prescribing or for rates of prescriptions dispensed by CVS .

21. If a MinuteClinic treats and/or refers a patient with an infectious and/ or contagious disease, the MinuteClinic shall notify the Rhode Island Department of Health and the state health department of the state to which they refer such a patient.

22. The applicant shall freely provide uncompensated care at MinuteClinics to patients who have been determined eligible for charity care as having income less than two hundred (200) percent of the poverty guidelines and who have documentation substantiating such charity care eligibility

from a Rhode Island hospital, community health center, free clinic or community mental health center. Such charity care requirement shall be limited to two (2) visits per year for each eligible patient and up to five percent (5%) of total annual visits to MinuteClinics system wide within the State.

[i] Alexander Blount, EdD. "The Necessity for Integrating Behavioral Health in Primary Care." Presentation to the Special Joint Commission to Study the Integration of Primary Care and Behavioral Health in RI, September 2013.

[ii] STARFIELD, B., SHI, L. and MACINKO, J. (2005), Contribution of Primary Care to Health Systems and Health. Milbank Quarterly, 83: 457–502. doi: 10.1111/j.1468-0009.2005.00409

[iii] Mostashari F Sanghavi I D McClellan M. Health Care Reform and Physician Led Accountable Care. The Paradox of Primary Care Physician Leadership. JAMA 2014;311(18) 1855-1856.

[iv] Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System.

[v] "Impact of Primary Care on Healthcare Cost and Population Health: A Literature Review," Rhode Island Department of Health. January 23, 2012; Schwenk TL. The Patient-Centered Medical Home: One Size Does Not Fit All. *JAMA*. 2014;311(8):802-803. doi:10.1001/jama.2014.352.

[vi] RI General Laws § 5-19.1-21(21) reads "On or after July 6, 1993, the board of pharmacy shall refuse to grant any pharmacy license to any individual who is a practitioner authorized to prescribe medications or to any partnership, corporation or other entity in which practitioners authorized to prescribe medications maintain a financial interest which, in the aggregate, exceeds ten percent (10%) of the total ownership of the entity or of the subject pharmacy or drug store"

[vii] Pediatrics "AAP Principles Concerning Retail-Based Clinics, Committee on Practice and Ambulatory Medicine." Vol. 3 No. 3, March 1, 2014 pp e794 – e797. published online February 24, 2014.

[viii] Statement of the Rhode Island Medical Society Regarding Retail-based Clinics, March 2014. https://www.rimed.org/pdf/pubs/HealthClinics0314.pdf accessed May 9 2014.

[ix] "Do Retail Clinics Increase Early Return Visits for Pediatric Patients?", J AM Board Fam Med; 21: 475-476 (2008) http://www.jabfm.org/content/21/5/475.full.pdf

[x] Tickner JA Kriebel1 D Wright S Int. J. Epidemiology. (2003) 32 (4): 489-492. doi: 10.1093/ije/dyg186

[xi] Centers for Disease Control and Prevention, Youth Behavioral Risk Behavior System

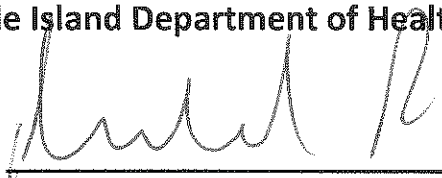
[xii] Alexander Blount, EdD. "The Necessity for Integrating Behavioral Health in Primary Care." Presentation to the Special Joint Commission to Study the Integration of Primary Care and Behavioral Health in RI, September 2013.

[xiii] Lasser, Karen E; S. Woolhandler; D. U. Himmelstein, "Sources of U.S. Physician Income: The Contribution of Government Payments to the Specialist-Generalist Income Gap." J Gen Intern Med. Sep 2008; 23(9): 1477-1481

The conditions set forth above shall be enforceable and have the same force and effect as if imposed as a condition of licensure, in accordance with Chapter 23-17 of the Rhode Island General Laws, as amended. The Director of the Rhode Island Department of Health may take appropriate action to enforce compliance with these conditions.

If any of the aforesaid conditions or the application thereof to any person or circumstances is held invalid, that invalidity shall not affect any other condition or application of any other condition which can be given effect without the invalid provision, condition, or application, and to this end the conditions and each of them severally are declared to be severable.

Rhode Island Department of Health



Michael Fine, MD
Director of Health

5/14/14

Date

ATTACHMENT A

Overview of Minute Clinic Scope of Services

Treatments and Services

Minor Illness Exams

-Allergy Symptoms

-Bronchitis/Cough

-Ear Ache/Ear Infection

-Flu-like symptoms

-Mononucleosis (Mono)

-Motion sickness prevention

- Pink eye & sties

-Sinus Infection/Congestion

-Sore throat/Strep

-Upper respiratory infection

-Urinary tract/ bladder infection

(Females 12 years +)

Minor Injury exams

-Bug bites and stings

-Jellyfish stings

-Minor Burns

-Minor cuts, blisters & wounds

-Splinter removal

-Sprain, strain (ankle, knee)

-Suture and staple removal

-Tick bites

-Camp physical

-Td (Tetanus, diphtheria)

-Sports physcials

Skin Condition Exams

-Acne

-Athlete's Foot

-Chicken Pox

-Cold, canker and mouth sores

-Impetigo

-Lice

-Minor rashes

-Poison Ivy/Oak

-Ringworm

-Scabies

-Shingles

-Sunburn

-Swimmers itch

-Wart evaluations (ages 5+)

-Health Screenings

-Basic Health Screening

-Cholesterol screening

-Comprehensive screening

-Glucose screening

-Weight loss program

-Physical exams

-PPSV

-DOT physical

Other

-Birth Control Injection

-Ear Wax removal

-Epi-pen refill

-Pregnancy evaluation

-Smoking cessation

-TB (Tuberculosis) testing

-Vitamin B12 injections

-Health Condition Monitoring

-A1c check

-High Cholesterol monitoring

-Diabetes monitoring

-Hypertension evaluation

-Vaccinations

-DTaP (diphtheria, tetanus, pertusis)

-Flu (Seasonal Adult & Child)

-Hepatitis A (Adult & Child)

-Hepatitis B (Adult & Child)

-HPV

-Polio

-Meningitis

-MMR (Measles, Mumps, Rubella)

-College & Administrative physical

- Tetanus, diphtheria pertusis

REPORT TO THE

HEALTH SERVICES COUNCIL

ON THE APPLICATION OF

MINUTECLINIC DIAGNOSTIC OF RHODE ISLAND, LLC

(OWNED BY MINUTECLINIC, LLC, WHICH IS OWNED BY CVS PHARMACY, INC.

WHICH IS OWNED BY CVS CAREMARK CORPORATION)

FOR INITIAL LICENSURE FOR SEVEN

ORGANIZED AMBULATORY CARE FACILITIES

IN WOONSOCKET, CRANSTON, NORTH SMITHFIELD, EAST GREENWICH,

PROVIDENCE, WAKEFIELD AND WESTERLY

Project Review Committee-II

Victoria Almeida (Ex-Officio)
John J. Barry III
Raymond Coia, Esq.
Steven R. DeToy
Joseph L. Dowling, MD
Catherine E. Graziano, RN, PhD
Robert Hamel, RN
Jeanette Matrone, RN, PhD
Daniel Orgel, MPA
Denise Panichas
Reverend David Shire (Ex-Officio)

Submitted to the
Health Services Council
29 April 2014

Adopted by the
Health Services Council
29 April 2014

TABLE OF CONTENTS

I. SYNOPSIS

Project Review Committee-II of the Health Services Council recommends that the applications of MinuteClinic Diagnostic of Rhode Island, LLC (owned by MinuteClinic, LLC, which is owned by CVS Pharmacy, Inc., which is owned by CVS Caremark Corporation) for initial licensure to establish seven Organized Ambulatory Care Facilities at 1054 Cass Avenue in Woonsocket, 681 Reservoir Avenue in Cranston, 120 Eddie Dowling Highway in North Smithfield, 1285 South County Trail in East Greenwich, 799 Hope Street in Providence, 11 Main Street in Wakefield, and 151 Franklin Street in Westerly be approved.

II. PROPOSAL DESCRIPTION

MinuteClinic Diagnostic of Rhode Island, LLC ("MCD RI" or the "applicant") is a Rhode Island for-profit limited liability company. MCD RI is a subsidiary of MinuteClinic, LLC. The proposal is for MCD RI to obtain seven Organized Ambulatory Care Facility ("OACF") licenses to establish MinuteClinic locations at 1054 Cass Avenue in Woonsocket, 681 Reservoir Avenue in Cranston, 120 Eddie Dowling Highway in North Smithfield, 1285 South County Trail in East Greenwich, 799 Hope Street in Providence, 11 Main Street in Wakefield, and 151 Franklin Street in Westerly.

MinuteClinic, LLC ("MinuteClinic"), is a Rhode Island for-profit limited liability company and is a wholly owned subsidiary of CVS Pharmacy, Inc. MinuteClinic is the largest retail health clinic system in the nation and provides care at over 800 locations in 28 states and the District of Columbia. It has provided 18 million visits since its founding in 2000. In Arizona, Florida, Massachusetts and New Hampshire, MinuteClinic operates pursuant to a license. In its remaining states, MinuteClinic is not required to possess a license to operate. MinuteClinic itself has not received any citations or violations.

CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island for-profit incorporation and is a wholly owned subsidiary of CVS Caremark Corporation ("CVS Caremark"). CVS Pharmacy operates more than 7,600 CVS Pharmacy and Longs Drug Stores. CVS Caremark is a Rhode Island for-profit corporation and is the largest integrated pharmacy company in the United States. CVS Caremark is a leading pharmacy benefit manager serving more than 60 million plan members.

According to the applicant, all MinuteClinic nurse practitioners and physician assistances ("practitioners") follow evidence-based, service-specific clinical guidelines, and, in Rhode Island, will treat patients 18 months and older, and will collaborate with Rhode Island-licensed physicians. MinuteClinic's scope of practice nationally includes diagnosis and treatment, including prescribing medications when appropriate, for common illnesses such as strep throat and ear, eye, sinus, bladder, and bronchial infections; treatment of minor abrasions and skin conditions; vaccinations such as influenza, tetanus, pneumonia, pertussis and Hepatitis A and B; walk-in camp, sports and college physicals; and wellness services designed to help patients identify lifestyle changes needed to improve their current and future health, including screenings

and monitoring for diabetes, high blood pressure and high cholesterol, and programs for weight loss and smoking cessation.

The expected hours of operation are 7 days per week, Monday through Friday 8:00 a.m. to 7:00 p.m., Saturday 9:00 a.m. to 5:30 p.m., and Sunday 10:00 a.m. to 5:30 p.m. MinuteClinic also has a team of medically-trained staff available by telephone for patient inquiries Monday through Friday 8:00 a.m. to 7:00 p.m., and Saturday and Sunday 10:00 a.m. to 7:00 p.m. Outside of these hours, MinuteClinic has two vendors who will provide call coverage and who forward all clinical questions to MinuteClinic licensed personnel. The vendors also respond to basic inquiries such as hours of operation and locations.

MCD RI will serve the geographic locations of 1054 Cass Avenue in Woonsocket, 681 Reservoir Avenue in Cranston, 120 Eddie Dowling Highway in North Smithfield, 1285 South County Trail in East Greenwich, 799 Hope Street in Providence, 11 Main Street in Wakefield, 151 Franklin Street in Westerly, and their surrounding areas.

The applicant's seven locations are estimated to begin services in 2014 if this proposal is approved. The locations in Woonsocket, Cranston, North Smithfield, and East Greenwich are planned to open approximately 60 days from the date of approval and the locations in Providence, Wakefield, and Westerly are planned to open throughout the remainder of 2014.

The 3-year projections for each individual MinuteClinic in the proposal are as follows:

FY	Operating Profit	# of Patients
2014*	$ (108,753)	1,953
2015	$ (217,085)	3,909
2016	$ (147,682)	4,760

*2014 ramp-up year

MinuteClinic is fully accredited by the Joint Commission.

III. INTRODUCTION

Pursuant to the requirements of Chapter 23-17 of the General Laws of Rhode Island entitled "Licensing of Health Care Facilities," the applicant filed an application for initial licensure to establish OACFs in Woonsocket, Cranston, North Smithfield, East Greenwich, Providence, Wakefield, and Westerly. This request is made because the statute requires that any proposed establishment of an OACF be reviewed by the Health Services Council and approved by the state-licensing agency prior to implementation.

Staff reviewed the application, found it to be acceptable in form, and notified the applicant and the general public by a notice on the Department's website and via direct mail and e-mail to interested persons that the review would commence on 6 March 2014. The notice also advised that all persons wishing to comment on the application submit their comments to the state agency by 5 April 2014, when practicable. Written and oral comments in support of this proposal were

made by the Greater Providence Chamber of Commerce Marie Ghazal, RN, MS, CEO of the Rhode Island Free Clinic, Ethan Berke, MD, Tod Podl, MD, OU Physicians, Virtua Health System, Laurie White, President of the Greater Providence Chamber of Commerce, Lynn Dunphy, PhD, Associate Dean of External Affairs at the University of Rhode Island, and Donna Policastro, Executive Director of the Rhode Island State Nurses Association. Written and oral comments in opposition of this proposal were made by Robert S. Crausman, MD, Elizabeth Lange, MD, and John Solomon, MD. Written and oral comments in relation to this proposal were made by Rhode Island Medical Society, Rhode Island Chapter of the American Academy of Family Physicians, Rhode Island Primary Care Physician Advisory Committee, Rhode Island Health Center Association, and William Hollinshead, MD, Vice President of the Rhode Island chapter of the Academy of Pediatrics (all written comments are attached and incorporated within this Report).

The Project Review Committee assigned to review this proposal met on 27 March 2014 and 17 April 2014 with the applicant in attendance at the meeting. At the 17 April 2014 meeting the Committee voted eight in favor, none opposed, and one recusal (8-0-1) to recommend that the proposal be approved subject to conditions of approval. In conjunction with her vote, Council member Panichas stated, "*I believe that the character, competency, standing in the community... I believe they have met that except for the pediatric care piece. I believe that in the future they could create a protocol that would be consistent with whatever the American Pediatric Association has, but I think that we have done a really good job of asking the questions. I am not necessarily sure I got all of the answers I wanted, but I see where the future role of all of this will be on the medical community to educate their patients about the difference between the care they provide and the care provided in a retail center. Traditionally we have done it the other way around, but now it's time to step up and educate your patients.*" Council member Coia stated, "*Based upon the criteria necessary to be met by the applicant, by the evidence submitted, I feel that, or I am of the opinion that, the review criteria have been met by the evidence put forth. I do take into consideration the comments by the doctors and all of those that may be opposed, and/or have questions relative to it, but after affording due weight to all of the evidence before this sub-committee, my vote is yes to approve.*" Acting Chair Reverend Shire stated, "*First of all, I am concerned about fragmentation to the patient care, having served on multiple ethics committees I don't feel that question was answered, at least to my satisfaction. I accept the fact that this is not a physician's office, and as I weigh all sides, I feel I have to come down on a yes, but I certainly hope the Director will consider the questions that are raised in my comments – the fragmentation and the ethics of the owner-operated facility.*"

IV. FINDINGS

Section 23-17-14.3 of the licensing statute requires the Health Services Council to consider specific review criteria in formulating a recommendation on applications for initial licensure.

A. The character, competence, commitment, and standing in the community of the proposed owners, operators or directors of the health care facility.

MinuteClinic Diagnostic of Rhode Island, LLC ("MCD RI") is a Rhode Island for-profit limited liability company. MCD RI is a subsidiary of MinuteClinic, LLC. The proposal is for MCD RI to obtain an Organized Ambulatory Care Facility ("OACF") license to establish MinuteClinic locations at 1054 Cass Avenue in Woonsocket, 681 Reservoir Avenue in Cranston, 120 Eddie Dowling Highway in North Smithfield, 1285 South County Trail in East Greenwich, 799 Hope Street in Providence, 11 Main Street in Wakefield, and 151 Franklin Street in Westerly.

Ownership

MinuteClinic, LLC ("MinuteClinic"), is a Rhode Island for-profit limited liability company and is a wholly owned subsidiary of CVS Pharmacy, Inc. MinuteClinic is the largest retail health clinic system in the nation and provides care at over 800 locations in 28 states and the District of Columbia. It has provided 18 million visits since its founding in 2000. In Arizona, Florida, Massachusetts, and New Hampshire, MinuteClinic operates pursuant to a license. In its remaining states, MinuteClinic is not required to possess a license to operate. MinuteClinic has not received any citations or violations.

CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island for-profit incorporation and is a wholly owned subsidiary of CVS Caremark Corporation ("CVS Caremark"). CVS Pharmacy operates more than 7,600 CVS Pharmacy and Longs Drug Stores. CVS Caremark is a Rhode Island for-profit corporation and is the largest integrated pharmacy company in the United States. CVS Caremark is a leading pharmacy benefit manager serving more than 60 million plan members.

The applicant has a sole member, MinuteClinic, and not a board of directors. MCD RI and MinuteClinic have elected the same individuals to serve as officers. MinuteClinic manages all of the business and affairs of the applicant. Andrew J. Sussman, MD serves as President of MinuteClinic and MCD RI and is the Senior Vice President and Associate Chief Medical Officer of CVS Caremark. No MinuteClinic or MCD RI officers serve as board members for either CVS Pharmacy or CVS Caremark. No board members of either CVS Pharmacy or CVS Caremark serve as officers of MCD RI.

MCD RI will hold the licenses for these facilities and will be separate and distinct from any licenses held by CVS Caremark and any of its subsidiaries. MinuteClinic practitioners follow evidence-based clinical guidelines, which are based on the scientific medical literature and recommendations of professional clinical and governmental organizations that are independent of CVS Caremark and any of its subsidiaries.

Scope of Services

Each facility will have a full time administrator and two full time registered nurse practitioners. All MinuteClinic nurse practitioners ("practitioners") follow evidence-based, service-specific clinical guidelines, and, in Rhode Island, will treat patients 18 months and older, and will collaborate with Rhode Island-licensed physicians. MinuteClinic's scope of practice nationally includes diagnosis and treatment, including

prescribing medications when appropriate, for common illnesses such as strep throat and ear, eye, sinus, bladder, and bronchial infections; treatment of minor abrasions and skin conditions; vaccinations such as influenza, tetanus, pneumonia, pertussis and Hepatitis A and B; walk-in camp, sports and college physicals; and wellness services designed to help patients identify lifestyle changes needed to improve their current and future health, including screenings and monitoring for diabetes, high blood pressure and high cholesterol, and programs for weight loss and smoking cessation.

The applicant represented that, for 2012 and 2013 system-wide, 0.9-1% of the total visits resulted in referrals to emergency rooms because the patient's condition was inappropriate for care in the retail clinic.

According to the applicant, MinuteClinic also promotes patient literacy and understanding through its partnership with the National Patient Safety Foundation and Ask Me 3 medical literacy program.

The expected hours of operation are 7 days per week, Monday through Friday 8:00 a.m. to 7:00 p.m., Saturday 9:00 a.m. to 5:30 p.m., and Sunday 10:00 a.m. to 5:30 p.m. MinuteClinic also has a team of medically-trained staff available by telephone for patient inquiries Monday through Friday 8:00 a.m. to 7:00 p.m., and Saturday and Sunday 10:00 a.m. to 7:00 p.m. Outside of these hours, MinuteClinic has two vendors who will provide call coverage and who forward all clinical questions to MinuteClinic licensed personnel. The vendors also respond to basic inquiries such as hours of operation and locations.

MCD RI will serve the geographic locations of 1054 Cass Avenue in Woonsocket, 681 Reservoir Avenue in Cranston, 120 Eddie Dowling Highway in North Smithfield, 1285 South County Trail in East Greenwich, 799 Hope Street in Providence, 11 Main Street in Wakefield, 151 Franklin Street in Westerly, and their surrounding areas.

The applicant's seven locations are estimated to begin services in 2014 if this proposal is approved. The locations in Woonsocket, Cranston, North Smithfield, and East Greenwich are planned to open approximately 60 days from the date of approval and the locations in Providence, Wakefield, and Westerly are planned to open throughout the remainder of 2014.

Oversight and Internal Review

MinuteClinic services are provided by nurse practitioners and physician assistants. The applicant represented that all of MinuteClinic's services can be legally provided in Rhode Island by a licensed nurse practitioner without any required physician chart review or supervision, but chart review will be performed as it is MinuteClinic's national model of care. Any services provided in Rhode Island by physician assistants will also be reviewed and supervised with appropriate physician oversight, as required by law. According to the applicant, all of MinuteClinic's services are within the scope of practice of nurse practitioners and physician assistants in Rhode Island.

The applicant represented that if internal review determines that other care was needed outside of the standard of care provided at the retail clinic, the senior nurse practitioner manager would be notified within 24 hours. The senior nurse practitioner would counsel the practitioner, ensure that appropriate recommendations are provided to the patient and any appropriate follow-up is performed, and ensure that the interaction was documents in the electronic medical record.

Laboratory Services

MCD RI practitioners will perform point-of-care tests that are all CLIA-waived tests, simple laboratory examinations and procedures that have an insignificant risk of erroneous result. Facilities performing waived tests are required to enroll in the CLIA program by obtaining a Certificate of Waiver that must be renewed every two years. The applicant represented that MinuteClinic will obtain Certificates of Waiver for each of its proposed locations. MinuteClinic utilizes two outside vendors, LabCorp and Quest Diagnostics, to perform confirmatory throat culture testing. Point-of-care tests that MinuteClinic will offer in Rhode Island are adeno test, lipid panel, blood sugar, HbA1C, flu test for Influenza A and B, urinary microalbumin, mononucleosis, pregnancy (urine), quick Strep, and urine dip stick.

Behavioral Health

MinuteClinic does not offer direct services concerning mental health care, substance abuse or addiction. The applicant represented that if MinuteClinic practitioners see a patient for some other service within its scope and the patient appears to have a mental health or substance abuse problem, the practitioner will refer the patient back to his or her primary care provider for evaluation. If the patient does not have a PCP, the practitioner will offer the patient a list of PCPs in the area who are accepting new patients, as well as information regarding community health center providers and the Rhode Island Free Clinic. If the patient presents with an emergent condition, such as suicidal ideation, MinuteClinic will refer the patient to the emergency department, or will contact 911, as appropriate. According to the applicant, MinuteClinic will work with local provider organizations to make sure referral to patients with mental health concerns is smooth and communicative.

Intake Process

MinuteClinic's intake process begins with the patient using a self-service, ADA-compliant, HIPAA compliant, touch screen kiosk. The patient enters demographic and medical insurance information and the general reason for his or her visit. At the beginning of the patient visit, the practitioner reviews and confirms the information entered into the kiosk, and asks any appropriate follow-up questions. All information obtained through the intake process is stored in a secure electronic medical record.

For the time period between 1 April 2013 and 31 March 2014, there was a system-wide average wait time for patients of 22 minutes.

The practitioner will provide the patient with a print out of his or her complete visit record at the conclusion of the visit, including all treatment and follow-up instructions.

Connection to Pharmacy

According to the applicant, there are no federal guidelines for retail-based clinics, and retail-based clinics are fully compliant with all state and federal statutes and regulations.

With respect to electronic prescriptions, for the time period 2011-2013, of the prescriptions that MinuteClinic practitioners wrote system-wide, the percentage directed to non-CVS pharmacies was between 18-19% for each of these years. The remaining percentage of electronic prescriptions was directed to CVS pharmacies.

Track Record

Representatives of MinuteClinic provided the following information.

MinuteClinic became the first retail clinic to achieve three consecutive accreditation awards from the Joint Commission. MinuteClinic earned the Joint Commission's Gold Seal of Approval by demonstrating compliance with the Joint Commission's national standards for health care quality and safety. Other recognitions and awards that MinuteClinic has received include Certified Continuing Education Provider from the American Nurses Credentialing Center, Nation's first retail clinic provider to implement the National Patient Safety Foundation's Ask Me 3 literacy program, National Influenza Vaccine Summit 2009 Immunization Excellence Award for a Corporate Campaign from the American Medical Association and the Centers for Disease Control and Prevention, and Certificate of Appreciation from the Center for Disease Control awarded to CVS Caremark and MinuteClinic for partnering as a National Influenza Group.

The applicant represented that a study published by James D. Woodburn, et al.[1], confirmed 99% adherence to clinical guidelines for sore throat care at MinteClinic. According to the applicant, in Minnesota, Minnesota Community Measurement publishes HEDIS quality results for public review, and MinuteClinic consistently appears at the top of the ranking for avoiding unnecessary antibiotics. The applicant represented that, in 2013, for treatment of acute bronchitis in adults, the average avoidance of antibiotics for all benchmark medical groups was 26%, while MinuteClinic's score was over 80%.

According to the applicant, MinuteClinic tracks patient satisfaction using data from Press Ganey, Inc., a patient satisfaction evaluation firm. According to this data, 93% of MinuteClinic patients report that they are satisfied with their provider. MinuteClinic also monitors its Net Promoter Score, which represents the willingness of a patient to recommend a provider to a friend or colleague. According to the applicant, MinuteClinic's Net Promoter Score for 2013 was 82%.

[1] James D. Woodburn, et al., Quality of Care in the Retail Health Care Setting Using National Clinical Guidelines for Acute Pharyngitis, *American Journal of Medical Quality*, Volume 22, 457 (December 2007).

Legal Proceedings

The applicant disclosed the following information in the applications.

In 1999 CVS Caremark was a defendant in qui tam lawsuit in Texas federal court. The case was unsealed in May 2005. The case sought monetary damages and alleged that CVS Caremark's processing of Medicaid and certain other government claims on behalf of its clients on one of CVS Caremark's adjudication platforms violated applicable federal or state false claim acts and fraud statutes. In December 2013 the case was dismissed following a settlement between CVS Caremark and the plaintiffs.

In a related matter, in December 2007 CVS Caremark received a document subpoena from the Office of Inspector General ("OIG") requesting information relating to the processing of Medicaid and other government agency claims on a different adjudication platform of CVS Caremark. CVS Caremark provided documents and has been conducting discussions with the United States Department of Justice and the OIG regarding a possible settlement of this matter.

In March 2010 CVS Caremark learned that various State Attorney General offices and other government agencies were conducting a multi-state investigation of certain CVS Caremark business practices similar to those being investigated at that time by the U.S. Federal Trade Commission ("FTC"). Twenty-eight states, the District of Columbia, and the County of Los Angeles are known to be participating in this investigation. The FTC investigation was concluded in May 2012 with a consent order entered into between the FTC and CVS Caremark. CVS Caremark has cooperated with the multi-state investigation.

In March 2010 CVS Caremark received a subpoena from the OIG requesting information about programs under which CVS Caremark has offered customers remuneration conditioned upon the transfer of prescriptions for drugs or medications to CVS Caremark's pharmacies in the form of gift cards, cash, non-prescription merchandise or discounts or coupons for non-prescription merchandise. CVS Caremark has provided documents and other information in response to this request for information.

In February 2011 CVS Caremark received a subpoena from the U.S. Securities and Exchange Commission ("SEC") and subsequently received additional subpoenas and other requests for information. The SEC's requests related to public disclosures made by CVS Caremark during 2009, transactions in CVS Caremark's securities by certain officers and employees of CVS Caremark during 2009 and the purchase accounting for the Longs Drug Stores acquisition. CVS Caremark has reached an agreement with the staff of the Boston Regional Office of the SEC to settle certain allegations that CVS Caremark violated provisions of the Securities Act of 1933 and the Securities Exchange Act of 1934, including certain anti-fraud provisions of those statutes. The agreement will be entered into by CVS Caremark on a "no admit or deny" basis, and CVS Caremark has agreed to pay a $20 million civil penalty when the settlement is finalized.

In 2012, the Department of Justice initiated an investigation under the Americans with Disabilities Act regarding an Arizona MinuteClinic patient contention of denial of service. The investigation was closed with no further action and no findings.

In January 2012 CVS Caremark received a subpoena from the OIG requesting information about its Health Savings Pass program in connection with an investigation of possible false or otherwise improper claims for payment involving Health and Human Services programs. In February 2012 CVS Caremark also received a civil investigative demand from the Office of the Attorney General of the State of Texas requesting a copy of the information produced under this OIG subpoena and other information related to prescription drug claims submitted by CVS Caremark's pharmacies to Texas Medicaid for reimbursement. CVS Caremark has provided documents and other information in response to this request for information.

In November 2012 CVS Caremark received a subpoena from the OIG requesting information concerning automatic refill programs used by pharmacists to refill prescriptions for customers. CVS Caremark has been cooperating and has provided documents and other information in response to this request for information.

Continuity of Care

MinuteClinic practitioners will document visit information electronically. These records will be shared, with the patients' consent, with the patient's primary care physician ("PCP") by fax and by participation in the Rhode Island Quality Institute's CurrentCare Health Information Exchange. According to the applicant, MinuteClinic also intends to enter vaccination data in the KidsNet vaccination data registry so that this data is widely available to PCPs. The applicant represented that MinuteClinic providers may also call sick patients at 48-72 hours after visits to confirm follow up.

Each practitioner will collaborate, and in the case of physician assistants will be supervised by a Rhode Island-licensed physician. During each visit the practitioner will determine if the patient has a PCP. If the patient has a PCP, the practitioner will, with the patient's permission, send the visit record to the PCP. If the patient does not have a PCP, the practitioner will offer the patient a list of PCPs in the area who are accepting new patients. The practitioner will provide the patient with a print out of their medical record including treatment instructions.

The applicant represented that MinuteClinic treats approximately half of its patients on evening and weekends, when primary care practices are often closed. In addition, holiday hours are also offered for patient access. According to the applicant, access to care at these times often complements and supports primary care medical home practices by allowing easy access to care outside of the Emergency Department.

According to the applicant, three published studies by Dr. James Rohrer of the Department of Family Medicine at the Mayo Clinic have shown that there is no evidence

that adult or pediatric retail clinic patients make an "early return" to physician offices of Emergency Departments after a retail clinic visit. These studies were based on chart review data and all conclude no evidence of an "early return" to primary care.

Local and National Collaborations

MinuteClinic, which is physician-led, has entered into clinical collaborations with 32 major health systems around the country, wherein the health systems physicians may serve as collaborating physicians for MinuteClinic practitioners, and MinuteClinic and the health systems pursue joint clinical programs and electronic medical record ("EMR") integration. MinuteClinic has integrated its electronic medical record with Allina Health System in Minnesota, Cleveland Clinic in Ohio, Cleveland Clinic in Florida, Emory Health System in Georgia, Florida Hospital in Florida, Parkridge Health System in Tennessee, Sharp Healthcare in California, and TriStar Health System in Tennessee.

According to the applicant, MinuteClinic has completed an affiliation agreement with a major Rhode Island health system to enhance coordination of care and collaboration, as well as integration of electronic medical records.

The applicant represented that MinuteClinic will be moving from its current proprietary EMR to the Epic EMR called EpicCare. Epic – the most widely used EMR in the United States – will facilitate connectivity with providers around the country that use Epic and other EMR systems, including many in Rhode Island. According to the applicant, these include Lifespan Health System, which will be implementing Epic over the next two years, and the Rhode Island Free Clinic.

According to the applicant, Rhode Island and New England area schools that have agreed or are in the discussion phase to collaborate as nursing rotation sites include University of Rhode Island (in discussion), Rhode Island College (in discussion), Boston College, Fairfield University, Massachusetts College of Pharmacy and Health Sciences, MGH Institute of Health Professionals, Northeastern University, Quinnipiac University, Sacred Heart University, Simmons College, University of Massachusetts – Amherst, University of Massachusetts – Boston, and University of Massachusetts – Worcester.

Supporting Comments

A 21 March 2014 letter of support from the Greater Providence Chamber of Commerce indicated that the model of MinuteClinic is cost effective, accessible, and evidence-based, and that MinuteClinics will serve the need of treating patients in an appropriate setting and not in an expensive hospital emergency room. At the 17 April 2014 meeting of the Project Review Committee-II, Laurie White, President of the Greater Providence Chamber of Commerce, made oral comments in support of this proposal. Ms. White indicated that MinuteClinics will be able to treat the otherwise "medically homeless."

At the 27 March 2014 and 17 April 2014 meetings of the Project Review Committee-II and in a 27 March 2014 letter of support, Marie Ghazal, CEO of the Rhode Island Free

Clinic ("RIFC"), indicated that RIFC had been struggling with its onsite pharmacy when CVS Caremark agreed to provide free medications to all RIFC patients. Ms. Ghazal stated that MinuteClinics will increase access for RIFC patients by being available to them in the evenings and on weekends with RIFC is closed. Ms. Ghazal indicated that uninsured patients treated at MinuteClinics will be referred to RIFC and MinuteClinics will then result in reduced cost for the uninsured with free care, medication, and services.

A 7 April 2014 letter of support from Ethan Berke, MD, MPH, indicated that in Dr. Berke's experience MinuteClinic provides high quality care through their use of guidelines imbedded in the electronic medical record. The letter represented that MinuteClinics support patients' needs and the patient-centered mission of Dartmouth-Hitchcock Medical Center.

An 11 April 2014 letter of support from Tod Podl, MD, MS, indicated that MinuteClinic is ahead of the curve compared to others in their training of staff, treatment algorithms, and patient satisfaction. The letter represented that Cleveland Clinic physicians have been very positive about the collaborative care between the Cleveland Clinic and MinuteClinic and have valued the electronic medical record integration that supports the partnership. The letter stated that a survey by the administration of the Cleveland Clinic revealed that 100% of Cleveland Clinic physicians find the quality of clinical care delivered at MinuteClinics to be very good to excellent.

A 15 April 2014 letter of support from Virtua Health System indicated that MinuteClinic provides excellent, accessible, and affordable care. The letter represented that despite initial apprehensions, the collaboration of Virtua Health System and MinuteClinic is now one of mutual respect and coordination in the care of patients. The letter stated that MinuteClinic fills in gaps in medical home practice and helps to meet patients' needs when Virtua Health System physicians might not be available.

A 15 April 2014 letter of support from OU Physicians indicated that the relationship between OU Physicians and MinuteClinic is collaborative and appropriately involves a medical team approach to the provision of care. The letter represented that as health care evolves, innovation and collaboration of the health care team is the necessary action to benefit the patients served.

At the 17 April 2014 meeting of the Project Review Committee-II and in a 17 April 2014 letter of support, Donna Policastro, Executive Director of the Rhode Island Nurses Association, indicated that the MinuteClinic model of care is in full alignment with the Nurse Practice Act and the APRN Consensus Model regarding Nurse Practitioner practice. Ms. Policastro stated that retail clinics are a safe and affordable option for ensuring access to care for our citizens as well as providing acute episodic care for international travelers, students, tourists, and seasonal employees. Ms. Policastro indicated that MinuteClinics in Rhode Island will provide Nurse Practitioner students with an additional preceptor site and model and provide Rhode Island employment opportunities to Nurse Practitioners who graduate from Rhode Island programs.

At the 17 April 2014 meeting of the Project Review Committee-II, Lynn Dunphy, PhD, Associate Dean of External Affairs at the University of Rhode Island, made oral comments in support of this proposal. Dr. Dunphy stated that MinuteClinics are cost effective, efficient, and provide greater access for patients.

Objections and Concerns

A 17 February 2014 letter of opposition from Robert S. Crausman, MD expressed concern regarding the ethical and financial conflicts that may negatively impact the patient-provider relationship. Dr. Crausman also wrote that the American Medical Association discourages physicians from engaging in retail sales due to ethical and financial conflicts.

A 20 March 2014 letter from the Rhode Island Medical Society raised concerns about the quality of care provided in MinuteClinics, proper communication with primary care providers, and MinuteClinic's ability to maintain standards of care. The letter also indicated that MinuteClinics take away from the comprehensive care of patients and promote fragmentation of care and decreased quality. The letter indicated that a MinuteClinic is not a proper source of care for patients under 6 years of age.

A 21 March 2014 letter from the Rhode Island chapter of the American Academy of Family Physicians indicated that the introduction of retail-based clinics into Rhode Island is disruptive to the medical home-patient relationship and is contradictory to initiatives to improve primary care. The letter also represented that medical care in a MinuteClinic is fractionated from a patient's medical home and could produce a risk for errors in communication between the retail-based clinic and a patient's primary care provider. The letter indicated that many patients still make an appointment with their primary care provider after their visit to a MinuteClinic, resulting in a second office visit for the same medical condition.

A 21 March 2014 letter from the Rhode Island Primary Care Physician Advisory Committee expressed concern that the MinuteClinic locations will be higher income and suburban areas, and not rural areas or areas near the Rhode Island Free Clinic. The letter represented that the nurse practitioner and physician collaboration is unclear in terms of chart review and onsite presence. The letter expressed concern regarding communication between the MinuteClinics and primary care providers as well as increased fragmentation of care. The letter indicated that providing health services in a building that also sells weight loss supplements and similar products is incongruent with the purpose of primary care provision and chronic disease management.

A 27 March 2014 letter from the Rhode Island Health Center Association requested conditions of approval be placed on this applicant. The letter expressed concern regarding communication between MinuteClinic and primary care providers, and that MinuteClinics should be a supplement to, and not a replacement for, primary care. The letter also requested referral agreements between the applicant and community health centers, as well as the Rhode Island Free Clinic.

At the 27 March 2014 and 17 April 2014 meetings of the Project Review Committee-II and in a 1 April 2014 letter of opposition, Elizabeth Lange, MD expressed concern regarding MinuteClinic's increasing fragmentation of care. Dr. Lange also indicated that there is no real collaboration between MinuteClinics and primary care providers, as MinuteClinics charge for services in which patient data is gathered, and then primary care providers must interpret that patient data for no additional pay. Dr. Lange also indicated that in the CVS in East Greenwich, there are posted advertisements for the opening of a MinuteClinic, despite the applicant not having yet received approval for this proposed facility.

At the 17 April 2014 meeting of the Project Review Committee-II, William Hollinshead, MD made oral comments regarding this proposal. Dr. Hollinshead requested that committee members consider what approval of this application implies for the health system in Rhode Island and what it means to add a third venue for health care for patients.

At the 17 April 2014 meeting of the Project Review Committee-II, John Solomon, MD made oral comments in opposition of this proposal. Dr. Solomon indicated that MinuteClinic locations will be charging more than primary care physicians are paid for the same services. Dr. Solomon indicated that he would not want his patients being treated elsewhere and doing so interrupts his ability to care for his patients. He indicated that he would consider no longer providing care to patients that have received care at a MinuteClinic location.

Finding: The Committee finds that the applicant satisfies this criterion at the time, place and circumstances as proposed.

B. The extent to which the facility will provide, without material effect on its viability, safe and adequate treatment for those individuals receiving the facility's services.

The proposed capital costs are $155,000, which will be provided through equity funds. CVS Caremark has sufficient resources to fund the required capital and operating needs, including cash on hand and access to both debt and equity capital.

The 3-year projections for each individual MinuteClinic in the proposal are as follows:

FY	Operating Profit	# of Patients
2014*	$ (108,753)	1,953
2015	$ (217,085)	3,909
2016	$ (147,682)	4,760

*2014 ramp-up year

Regarding the projected operating losses, MinuteClinic continues to maintain sufficient funds to finance these clinics from cash on hand generated by other clinics and still has access to additional funds from CVS Caremark should unexpected expenses arise.

To reduce the cost of care, the applicant represented that MinuteClinic employs a single-provider model, that is, a certified registered nurse practitioner or physician assistant who will perform the administrative and clinic functions at each Rhode Island location. Patients will check in using a self-service kiosk eliminating the need for front desk personnel, lowering the cost of care.

According to the applicant, one of the main drivers of cost in ambulatory care is provider salaries. A nurse practitioner or physician's assistant costs approximately half the amount in salary to employ as compared to a physician, and it takes approximately two-to-three full-time equivalent personnel to support a physician. Through the use of the single-practitioner model, the applicant represented that MinuteClinic can efficiently utilize appropriate-level practitioners with the use of well-defined and limited scope of service. According to the applicant, this results in lower costs, which MinuteClinic can pass on to its patients in the form of lower prices.

In addition, the applicant represented that because MinuteClinic has centralized corporate functions, the overhead costs associated with practice, e.g., providing revenue cycle and operational support, are comparatively lessened for each provider site. MinuteClinic also utilizes an existing retail facility – the OACF will be located in a CVS Pharmacy store – eliminating the need for significant, additional infrastructure expenditure. According to the applicant, MinuteClinic's use of a single electronic medical record system also eliminates the need for costly document storage.

According to the applicant, evidence-based clinical practice guidelines help lower costs by standardized practice, reducing variation, and highlighting cost-effective solutions.

A 2009 Rand-sponsored study[2] found MinuteClinic's costs to be 40-80% less expensive than alternate sites of care and equal or better in quality. Pharmacy costs were the same or lower for patients treated at MinuteClinic.

According to a 2013 study[3] published in *The American Journal of Managed Care*, comparing MinuteClinic users to non-users (matching the groups on over 500 demographic, health status and care seeking characteristics), utilization of physician visits, emergency department visits and hospital care were all lower for MinuteClinic patients, and adjusted total costs of care for MinuteClinic users were 8% lower than for those who did not use MinuteClinic.

---

[2] Ateev Mehrotra, MD, Hangsheng Liu, PhD, John L. Adams, PhD, et al., *Comparing Costs and Quality of Care at Retail Clinics With That of Other Medical Settings for 3 Common Illnesses*, Annals of Internal Medicine, Volume 151:5, 321-328 (September 2009).

[3] Andrew J. Sussman, MD, Lisette Dunham, MSPH, Kristen Snower, MBA, et al., *Retail Clinic Care Associated with Lower Total Cost of Care*, American Journal of Managed Care, Volume 19:4, 148-157 (April 2013).

The Committee was not made aware of any adverse financial circumstances related to the applicant.

Finding: The Committee finds that the applicant satisfies this criterion at the time, place and circumstances as proposed.

C. The extent to which the facility will provide safe and adequate treatment for individuals receiving the health care facility's services.

See (A) above.

Finding: The Committee finds that the applicant satisfies this criterion at the time, place and circumstances as proposed.

D. The extent to which the facility will provide appropriate access to traditionally under-served populations.

Payor Mix and Charity Care

The payor mix as projected for the proposed OACFs in each individual location is as follows:

PAYOR SOURCE	RAMP UP YEAR 2014				FIRST FULL FISCAL YEAR 2015			
	Units of Service (Visits)		NET PATIENT REVENUE		Units of Service (Visits)		NET PATIENT REVENUE	
	#	%	$	%	#	%	$	%
Medicare	142	6%	$9,450	6%	284	6%	$18,900	6%
Medicaid	24	1%	$1,575	1%	47	1%	$3,150	1%
Blue Cross	804	34%	$53,550	34%	1,608	34%	$107,100	34%
Commercial	1,088	46%	$72,450	46%	2,175	46%	$144,900	46%
Self Pay	307	13%	20,475	13%	615	13%	$40,950	13%
TOTAL:	**2,364**	**100%**	**$157,500**	**100%**	**4,729**	**100%**	**$315,000**	**100%**

According to the applicant, MinuteClinic will accept all major payers, including Rhode Island Medicaid, Medicaid managed care plans, Health Care Exchange Insurance Plans, Medicare and Medicare Advantage plans, as well as others. The applicant represented that MinuteClinic's discussions with these payers, including Blue Cross Blue Shield of Rhode Island, are ongoing. MinuteClinic refers patients to the health plans regarding patient-specific coverage questions. For cash-pay services, prices are transparently posted and patients are notified in advance of need of payment.

MinuteClinic has committed to provide up to $100,000 of free care in its Rhode Island clinics to patients registered as active patients of the Rhode Island Free Clinic ("RIFC"), a health care provider for uninsured adults, located at 655 Broad Street in Providence. This is approximately $14,285 per location (annualized to $1,191 per month per location). Applying these values will result in charity care representing 5% of patient revenue at the proposed facility and charity chare projected as 5% of total number of cases in 2014 and 2015.

MinuteClinic practitioners will identify patients by their RIFC card and by a patient roster that will be provided by the RIFC. According to the applicant, MinuteClinic practitioners will care for the patient, and MinuteClinic will coordinate with RIFC regarding follow-up care, and, as appropriate, and with patient consent, send the patient's notes to RIFC. CVS Pharmacy will provide these patients with free prescription medications.

According to the applicant, CVS Caremark plans to support local health care programs such as the Thundermist Health Center in Woonsocket.

The applicant represented that in the past five years, CVS Caremark has donated $4.5 million to support Rhode Island health care initiatives and organizations such as the Rhode Island Quality Institute, Bradley Hospital, Hasbro Children's Hospital, Miriam Hospital, and Rhode Island Free Clinic.

In December 2013, The CVS Caremark Charitable Trust, a private foundation created by CVS Caremark, announced a $5 million commitment to expanding access to quality health care nationwide through partnerships with the National Association of Free and Charitable Clinics, and School-Based Health Alliance and the second year of the "Innovations of Community Health" grant program in partnership with the National Association of Community Health Centers. Beginning in 2014, grants will be made available to free and charitable clinics, school-based health centers, and community health centers nationwide to increase access to health care and coordinated care to improve health outcomes for people of all ages, across the country.

According to the applicant, CVS Caremark partners with the National Association of Community Health Centers to support innovative solutions for people for chronic disease management.

The applicant represented that in 2014, CVS Caremark will deliver more than $15 million worth of free health services to multicultural communities across the United States through its Project Health campaign. Project Health offers an array of free comprehensive health risk assessments, including blood pressure, Body Mass Index, glucose, and total cholesterol screenings.

National Culturally and Linguistically Appropriate Services ("CLAS") Standards in Health and Health Care

The applicant identified how they comply with each of the CLAS standards.

Practitioners and MinuteClinic Call Center employees utilize an interpreter service, LanguageLine Solutions, to deliver quality health care services to MinuteClinic patients or family members with limited English proficiency. According to the applicant, MinuteClinic provides guidance to employees on how to effectively utilize interpreter services to ensure a positive patient experience, including clarity about services offered at

MinuteClinic. LanguageLine Solutions service is available in all MinuteClinic locations and the MinuteClinic Call Center and is provided at no additional cost to the patient. This service provides translation of 200 languages. MinuteClinic also has available Spanish versions of its patient brochures.

According to the applicant, MinuteClinic also utilizes American Sign Language ("ASL") interpreters to assist hearing-impaired patients. If a patient requires the services of ASL, MinuteClinic will schedule an appointment to ensure the interpreter is available for the patient's visit. This service is provided at no additional cost to the patient. The applicant represented that for hearing-impaired patients, the practitioners and call center staff utilize the Telecommunication Relay Service to communicate with hearing-impaired patients by phone. In addition, MinuteClinic has the capability to provide a patient summary visit in Braille, which is provided at no additional cost to the patient.

Transportation

According to the applicant, 5 out of 7 of the proposed locations are accessible by bus. These locations are the proposed facilities in Woonsocket, Cranston, North Smithfield, Providence, and Wakefield.

Geographic Location

According to the U.S. Department of Health and Human Services, Health Professional Shortage Areas affect the proposed facilities in Woonsocket and Providence.

Facility Design

Each proposed location is handicapped accessible and in compliance with the Americans with Disabilities Act ("ADA"). There are public restrooms conveniently located near the clinics within each of the CVS locations and the applicant represented that these bathrooms will be easily accessible for MCD RI patients. Each proposed facility meets the *"Guidelines for Design and Construction of Healthcare Facilities" (2010 edition)* except for a few areas. The architect, William Starck Architects, Inc., has submitted a formal variance request to the Rhode Island Department of Health Office of Facilities Regulation. The areas regarding which MCD RI is seeking variances have either an alternative to the guidelines or an explanation of why the health, safety or welfare of individuals and the quality of services or treatment provided will not be compromised by these variances. The same floor plans have previously been reviewed and approved for accreditation by the Joint Commission in other states.

The proposed facilities located in Woonsocket, Cranston, North Smithfield, East Greenwich, and Westerly have been constructed. The proposed facilities in Providence and Wakefield have not begun construction. These locations are expected to start construction on 2 June 2014 and end construction on 27 June 2014. The cost of funding their construction is approximately $155,000 per clinic.

Finding: The Committee finds that the applicant satisfies this criterion at the time, place and circumstances as proposed.

V. RECOMMENDATION

After considering each of the review criteria as required by statute and the representations made by the applicant, the Project Review Committee recommends that this request for initial licensure be approved.

VI. CONDITIONS OF APPROVAL

It is recommended that approval of the instant application shall be subject to the following conditions:

1. That the applicant establish and put into effect formal agreements for referral of charity care cases with a minimum of one licensed free clinic within sixty (60) days of approval;

2. that the facility maintain accreditation from a nationally recognized accrediting agency;

3. that the applicant shall conduct national background checks on its employees; and

4. that the facility will provide data to the state agency, if requested and prescribed by the state agency.